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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

KENNETH LEVI PACK, an individual, on behalf of himself and all others similarly situated; MIN JI JUNG, an individual, on behalf of herself and all others similarly situated,

Plaintiff,

v.

Johnson & Johnson Consumer Companies, Inc.; GlaxoSmithKline LLC; Reckitt Benckiser LLC; Bayer HealthCare LLC; Sanofi- Aventis U.S. LLC; The Procter & Gamble Company; Church & Dwight Co., Inc.; Walmart Inc.; Target Corporation; CVS Pharmacy, Inc.; Walgreen Co.; Albertsons Companies Inc.; Rite Aid Corporation; Amazon.com, Inc.; and Does 1-20,

Defendants.

Case No. 2:23-cv-01965-TLN-AC

CHURCH & DWIGHT CO., INC.'S MEMORANDUM OF POINTS & AUTHORITIES IN SUPPORT OF ITS MOTION TO DISMISS

Hon. Troy L. Nunley

Courtroom 2, 15th Floor

Date: December 14, 2023

Time: 2:00 pm

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Church & Dwight Co., Inc. ("Church & Dwight") submits this Memorandum of Points and Authorities in support of its motion to dismiss Plaintiffs' Complaint.

I. PRELIMINARY STATEMENT

In a rush to join the dozens of phenylephrine cases recently filed across the country, Plaintiffs' counsel scoured the internet for any nasal decongestant ever sold that might have contained phenylephrine. They then sued 15 purported makers of phenylephrine nasal decongestants, including Church & Dwight. However, what sets Church & Dwight apart from the other defendants is that it never sold any of the products at issue. Plaintiffs are suing Church & Dwight because it acquired the Zicam brand, which sold a few products purportedly containing phenylephrine ("Purported Zicam PE Products") in the early 2000s. ***Zicam discontinued those products more than a decade ago.***

Fatally, and contrary to established pleading requirements, Plaintiffs do not allege they bought any Purported Zicam PE Products. The Complaint thus fails to plead any injury in fact to support Article III standing. Nor can Plaintiffs plead injury in fact in any amended complaint as evidenced by their inability to respond to Church & Dwight's pre-motion request for basic information surrounding any purchases of the Purported Zicam PE Products. Indeed, Plaintiffs could not answer threshold questions asking which, if any, Zicam products they bought, when they allegedly bought them and where they bought them. This is no surprise since few people, if any, would recall buying a particular cold relief product 15 or 20 years ago.

This passage of time dooms Plaintiffs' claims against Church & Dwight for another reason. Because any purchases that Plaintiffs might have made of the Purported Zicam PE Products would have been well over a decade ago, the relevant statutes of limitations have lapsed. The Complaint tries to sidestep this fatal deficiency through boilerplate, conclusory assertions in support of tolling. But Plaintiffs do not explain why, with reasonable diligence, they could not have uncovered the alleged "fraud" during the limitations period. Nor can Plaintiffs make such allegations in an amended

complaint because the efficacy of orally administered phenylephrine has been publicly debated for years, which, at a minimum, should have caused Plaintiffs and their counsel to investigate the issues alleged in the Complaint. Plaintiffs' claims against Church & Dwight are therefore time-barred.

Plaintiffs' purported claims also fail for several more reasons not unique to Church & Dwight. First, Plaintiffs' claims are preempted. For decades, the U.S. Food and Drug Administration has approved of orally administered phenylephrine products being marketed as nasal decongestants. FDA regulates nasal decongestants under its Nasal Decongestant Final Monograph ("OTC Monograph"). The OTC Monograph recognizes that orally administered phenylephrine is a safe and effective nasal decongestant. It expressly permits orally administered phenylephrine products to be marketed as "nasal decongestants" and specifies the requirements for labeling of these products. Plaintiffs do not and cannot claim that the Purported Zicam PE Products violated the OTC Monograph. As a result, Plaintiffs' purported state law claims challenging the products' FDA-approved labeling are preempted by the FDCA.

Second, the Complaint does not allege any plausible basis to infer that the Purported Zicam PE Products were ineffective for their advertised (and FDA-approved) purpose. The Complaint claims that "[o]n or about September 12, 2023, the Federal Drug Administration [sic], after careful study and consideration, announced publicly that phenylephrine is ineffective as a treatment for [nasal congestion]." Complaint ¶ 3. That is simply wrong. Indeed, the very announcement that the Complaint incorporates by reference says that FDA itself has *not* made any determination on this issue.[1] Rather, an FDA advisory committee—not FDA itself—believes "the current scientific data do not support that the recommended dosage of orally administered phenylephrine is effective as a nasal decongestant." *Id.* At best, this announcement might indicate that the efficacy of phenylephrine is subject to scientific debate, or maybe that the evidence

[1] Ex. 1, U.S. Food & Drug Administration, *FDA clarifies results of recent advisory committee meeting on oral phenylephrine* (Sept. 14, 2023), https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-results-recent-advisory-committee-meeting-oral-phenylephrine.

is inconclusive, but California law prohibits private litigants from bringing such "lack-of-substantiation" claims.

Third, the Complaint flouts Rule 9(b)'s requirement to plead with particularity the facts of an allegedly fraudulent product sale. Plaintiffs not only fail to identify any Purported Zicam PE Products they bought, but also fail to say when or where any such transactions occurred, and what label or advertising statements deceived them.

Plaintiffs' claims against Church & Dwight should be dismissed for each of the foregoing independent reasons. And they should be dismissed with prejudice because amendment would be futile. But if any part of the Complaint does survive, this case should be stayed under the doctrine of primary jurisdiction while FDA reviews the efficacy of phenylephrine.

II. STATEMENT OF FACTS[2]

Church & Dwight acquired the Zicam brand in 2020. The Zicam brand is best known for zinc lozenges that help to shorten the common cold. Those products do not contain phenylephrine and are not at issue here.

The Complaint does not name any of the Purported Zicam PE Products. But Plaintiffs' counsel informed Church & Dwight's counsel after filing suit that "[their] research indicates that Zicam medicated spoons contain phenylephrine as an active ingredient." Ex. A. Even if that "research" were accurate, and even if the "medicated spoons" were the Zicam products that the Complaint intended to address, those products were discontinued by 2010, if not sooner. Neither Zicam nor Church & Dwight has sold any orally administered phenylephrine products since then.

At all relevant times, the Purported Zicam PE Products were marketed under, and in compliance with, the OTC Monograph that FDA issued in 1994.[3] The OTC Monograph resulted from an extensive review process that involved outside experts and

[2] Exhibits 1-22 are attached to Church & Dwight's Request for Judicial Notice. Exhibits A and B are attached to the Declaration of Jeffrey H. Warshafsky ("Warshafsky Decl.").

[3] The final monograph (Ex. 2) was published at 21 C.F.R. § 341.80, and pursuant to OTC monograph reform legislation is now available at https://dps.fda.gov/omuf/monographsearch/monograph_m012.

a thorough review of studies on the safety and efficacy of various ingredients, including phenylephrine. *See* 41 Fed. Reg. 38,312, 38,314.

Under the OTC Monograph, orally administered phenylephrine products must be identified as a "nasal decongestant" and the product's use must be described as being "[f]or the temporary relief of nasal congestion" (or "[t]emporarily relieves nasal congestion") "due to" "the common cold" (or "a cold" or due to hay fever allergies). 21 C.F.R. § 341.80. Plaintiffs do not (and cannot) allege that the Purported Zicam PE Products violated these or other OTC Monograph requirements.

This lawsuit, and the many others like it, were spurred by the September 12 announcement that an FDA advisory committee believes the current scientific data does not support the efficacy of the recommended dosages of orally administered phenylephrine for reducing nasal congestion. At least 30 makers of such products have been sued in at least 81 lawsuits following this announcement.[4] Church & Dwight has been named as a defendant only in this case and the *McPhee* action,[5] both filed by the same counsel, Singleton Schreiber.

In the Complaint, Plaintiffs vaguely allege they "purchased the Phenylephrine Products, and each of them" at some unidentified time and place "within the statutory time period." Complaint ¶¶ 7, 9. The Complaint defines the "Phenylephrine Products" as all "products containing phenylephrine—a purported decongestant used as an active ingredient in at least 250 products, including without limitation Sudafed Sinus Congestion, Tylenol Cold & Flu Severe, Nyquil Severe Cold & Flu, Theraflu Severe Cold Relief, Mucinex Sinus Max, and many others, including generic brands developed by major retailers like CVS, Walmart, Target and Walgreens." *Id.* ¶ 1.

The Complaint does not identify which, if any, Purported Zicam PE Products Plaintiffs allegedly bought, or when or where they bought them. In fact, Plaintiffs do

[4] These cases are now before the Judicial Panel on Multidistrict Litigation on a motion for consolidation. *In re: Oral Phenylephrine Marketing and Sales Practices Litigation*, MDL No. 3089 (J.P.M.L. filed Sept. 18, 2023).

[5] *McPhee v. Johnson & Johnson Consumer Cos.*, No: 3:23-cv-05128 (N.D. Cal. filed Oct. 6, 2023).

not specifically allege that they bought any Purported Zicam PE Products. The Complaint's only allegation relating to Zicam is that "[a]t all times relevant to this complaint, Church & Dwight was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the Phenylephrine Products, including but not limited to, Zicam." *Id.* ¶ 16.

Skeptical that Plaintiffs ever purchased the Purported Zicam PE Products at issue, before filing this motion, Church & Dwight asked Plaintiffs to provide details about any alleged purchases of the Purported Zicam PE Products. Ex. B. Plaintiffs could not do so. Warshafsky Decl. ¶ 3. Even so, this much is known: If Plaintiffs ever did buy such products, it would have been over a decade ago since no Purported Zicam PE Products have been marketed in the U.S. since at least 2010.

To argue their claims are not time-barred, Plaintiffs claim they "could not have discovered, through the exercise of reasonable due diligence, that the active ingredient in the Phenylephrine Products was ineffective." Complaint ¶ 48. Plaintiffs also assert that "[a]ll applicable statutes of limitations have also been tolled by Defendants' fraudulent concealment and misrepresentations about the effectiveness of phenylephrine and the Phenylephrine Products throughout the time period relevant to this action." *Id.* ¶ 49. But Plaintiffs plead no facts to support either tolling theory.

Nor could Plaintiffs credibly claim that the alleged inefficacy of orally administered phenylephrine was a secret until 2023. There are published scientific articles questioning the efficacy of phenylephrine going back to at least 2006. Exs. 3-7. And this issue has been the subject of public debate for at least 17 years. For instance:

- In an August 2006 letter, Representative Henry Waxman publicly called on FDA to investigate the efficacy of orally administered phenylephrine in light of a recently published study. Ex. 8. FDA publicly responded that it was declining to take action. Ex. 9.
- FDA received a citizen's petition in February 2007 from a group of pharmacists that questioned phenylephrine's recommended dosage.

Ex. 10. After a panel of outside experts investigated, they voted that phenylephrine was effective at the recommended dosage. Nevertheless, the panel acknowledged there was uncertainty, with members stating that the existing studies "would not meet today's standards of evidence" (Ex. 11) and were "murky" (Ex. 12).

- Yet another citizen's petition was filed by some of the same pharmacists in November 2015. This petition requested that FDA "remove oral phenylephrine from the Final Monograph for OTC nasal decongestant products," citing various published studies purportedly showing the inefficacy of orally administered phenylephrine. Ex. 13. It was this petition that resulted, eight years later, in the 2023 advisory committee meeting that prompted this lawsuit and others like it.

All of this was widely reported in the media, was discussed at public meetings held by FDA, and was the subject of hearings and testimony before Congress. Exs. 8-19. Indeed, in a substantial number of the other recent phenylephrine lawsuits, the complaints allege that its efficacy has been doubted since at least 2007.[6] As a result, Plaintiffs do not and cannot plausibly allege that they could not have discovered the public debate over this issue—and could not have brought their purported claims—until now.

Despite questions over the years about the efficacy of orally administered phenylephrine, the OTC Monograph was in place throughout the time the Purported Zicam PE Products were sold. Indeed, it remains in effect today. In response to the advisory committee's recent concerns, FDA has stated that it "will consider the input of this advisory committee, and the evidence, before taking any action on the status of oral phenylephrine." Ex. 1. FDA also clarified that "[a]dvisory committees provide independent advice and recommendations to FDA, *but the agency makes the final decision*." *Id.* (emphasis added).

[6] *E.g.*, Complaint ¶ 6, *Barton v. RB Health (US) LLC*, No. 2:23-cv-20370 (D.N.J. filed Sept. 14, 2023) ("Since at least 2007, scientific studies using modern testing methodologies and rigors have, time and again, shown that phenylephrine taken orally is ineffective.").

FDA's review of this matter is active and ongoing. For example, FDA opened a docket for the advisory committee which has received several comments. Ex. 20. Some have urged FDA not to modify the OTC Monograph given evidence that phenylephrine is an effective nasal decongestant. Ex. 21. And on September 29, 2023, FDA posted its Annual Forecast for Planned Monograph Activities, which lists "Address[ing] the GRASE status of OTC phenylephrine as an oral decongestant ingredient" as a planned activity. Ex. 22. In the meantime, orally administered phenylephrine remains on the OTC Monograph as an FDA-approved safe and effective nasal decongestant.

III. ARGUMENT

A. Plaintiffs Lack Standing to Sue Church & Dwight Because They Did Not Buy Any Purported Zicam PE Products

A Rule 12(b)(1) motion challenges a court's subject matter jurisdiction to hear the plaintiff's claims. If a plaintiff lacks standing under Article III of the U.S. Constitution, then the court lacks subject matter jurisdiction, and the case must be dismissed. *See Bates v. UPS, Inc.*, 511 F.3d 974, 985 (9th Cir. 2007). To establish Article III standing, a plaintiff must show that she: (1) has suffered an "injury in fact" that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, not merely speculative, that the injury will be redressed by a favorable decision. *Friends of the Earth, Inc. v. Laidlaw Env't. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000). Standing is a threshold question, and plaintiff bears the burden of establishing it. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992).

To potentially have Article III standing to sue for alleged false advertising of a product, a named plaintiff in a putative class action must have bought that product. And a plaintiff cannot circumvent this requirement with vague and conclusory allegations. For instance, a court *sua sponte* dismissed a complaint for lack of subject matter jurisdiction in which the plaintiff alleged he bought "an assortment of flavors of the

Nova Kombucha" but did not identify which ones. *Renn v. Otay Lakes Brewery, LLC*, 2023 U.S. Dist. LEXIS 164334, at *5 (S.D. Cal. Sept. 14, 2023).

Many other courts have also concluded that a plaintiff cannot sue a defendant for alleged false advertising unless the plaintiff bought the product in question and so alleges. *E.g.*, *Machlan v. P&G*, 77 F. Supp. 3d 954, 963 (N.D. Cal. 2015) ("While the Court finds for the reasons below that plaintiff has alleged enough to proceed against P&G at this point for the Pampers wipes, the Court does not find that plaintiff may also proceed against P&G for the Charmin wipes, which he concedes he did not purchase"); *Ivie v. Kraft Foods Glob., Inc.*, 2013 U.S. Dist. LEXIS 25615, at *13 (N.D. Cal. Feb. 25, 2013) (emphasis in original) ("[T]here can be no requisite *pecuniary* injury where plaintiff did not herself purchase the product at issue"); *Murray v. Elations Co.*, 2014 U.S. Dist. LEXIS 107721, at *32 (S.D. Cal. Aug. 4, 2014) (dismissing complaint for lack of standing because plaintiff did not plausibly allege "that he was exposed to and relied on" the defendants' allegedly false advertisements).

This is an even easier case. Plaintiffs hide behind vague shotgun allegations about every phenylephrine product ever sold, claiming they "purchased the Phenylephrine Products, and each of them" at some unidentified time. Complaint ¶¶ 7, 9. ***But Plaintiffs do not allege they bought any specific Purported Zicam PE Products.*** Indeed, Plaintiffs do not even allege that they bought unnamed "Zicam products," which would still be insufficient as explained in *Renn* and the other cases cited above. For this reason alone, Plaintiffs do not even get past square one for standing.

Even if Plaintiffs had actually bought any Purported Zicam PE Products, they still suffered no injury unless the products were ineffective for them. If the products worked, they got what they paid for. But Plaintiffs make no allegations about this either, yet another reason they lack standing to sue on these products.[7]

[7] If Plaintiffs do claim that they used the Purported Zicam PE Products and found them to be ineffective, then they have no excuse for delaying to raise this issue for years since it would have been "discoverable" shortly after their use of their products. *See* pp. 11-13, *infra*.

Ultimately, the Complaint does not pass the smell test. The Complaint claims that each Plaintiff bought and used "each" of the "Phenylephrine Products" (Complaint ¶¶ 7, 9), defined as all 250+ decongestant products containing phenylephrine (*id.* ¶ 1). But it is facially implausible that any individual consumer has bought 250+ phenylephrine products. Such an unbelievable assertion is entitled to no weight. *See Ashcroft v. Iqbal*, 556 U.S. 662, 664 (2009) (a court should "draw on its experience and common sense"). It is obvious that Plaintiffs simply sued every company who ever made a phenylephrine product no matter if they bought it.[8]

Likewise, it defies credulity that a consumer would recall which specific cold remedy product they bought over a decade ago, never mind the circumstances surrounding their purchase and use of such product.[9] A consumer might recall having bought a "Zicam" product at some point, but the Purported Zicam PE Products have not been sold in over a decade and even then, they were a small part of the Zicam product line. Thus, if Plaintiffs truly claim to have bought the Purported Zicam PE Products, as opposed to other Zicam products that do *not* contain phenylephrine, they must allege those facts—assuming they can do so in compliance with Rule 11. *See Dakus v. KLM*, 2023 U.S. Dist. LEXIS 161312, at *19 (S.D.N.Y. Sept. 12, 2023) (ordering plaintiff's counsel to show cause why Rule 11 sanctions should not be levied against him due to his failure to investigate whether his client in fact made a purchase from the defendant).

But Plaintiffs cannot make such allegations. Before making this motion, Church & Dwight asked Plaintiffs to identify the specific Zicam product(s) they bought and the date and location of purchase. Ex. B. Plaintiffs provided no information in response to this request. Warshafsky Decl. ¶ 3. Their inability to identify any Purported Zicam PE Products they bought confirms that they cannot cure their deficient allegations against Church & Dwight. Thus, amendment would be futile and the Complaint should be

[8] If credited, the assertion that Plaintiffs bought 250+ different phenylephrine products would strongly suggest that the products worked for them, in which case they would lack standing to sue.

[9] This also precludes any possibility of certifying a class based on claims involving the Purported Zicam PE Products, an issue beyond this motion but one that looms large in this case.

dismissed with prejudice. *Carvalho v. Equifax Info. Servs., LLC*, 629 F.3d 876, 893 (9th Cir. 2010).

If the Court is not yet inclined to dismiss with prejudice, Church & Dwight respectfully requests the opportunity to renew its Rule 12(b)(1) motion following jurisdictional discovery from Plaintiffs focused on whether they bought any Purported Zicam PE Products. Such discovery is warranted when "pertinent facts bearing on the question of jurisdiction are controverted or where a more satisfactory showing of the facts is necessary." *Twentieth Century Fox Int'l Corp. v. Scriba*, 385 F. App'x 651, 652 (9th Cir. 2010). *See also Johnson v. Right Crons Inc.*, 2022 U.S. Dist. LEXIS 113274, at *11 (N.D. Cal. June 27, 2022) (awarding jurisdictional discovery to determine whether plaintiff in fact visited defendant's establishment and thus had standing to sue).

B. Plaintiffs Fail to State a Claim Against Church & Dwight for Several Independent Reasons

A complaint must be dismissed under Rule 12(b)(6) if it fails to state a cognizable legal theory, or to allege sufficient facts to support a legal theory, *Balistreri v. Pacifica Police Department*, 901 F.2d 696, 699 (9th Cir. 1988), or if it does not offer enough facts to state a plausible claim for relief, *Bell Atlantic Co. v. Twombly*, 550 U.S. 544, 558-59 (2007). A claim is implausible "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct." *Iqbal*, 556 U.S. at 679. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 678. Only after the complaint has been "[t]rimmed of 'legal conclusions' and 'threadbare recitals of a cause of action'" does the court determine whether it "contains sufficient factual allegations to state a plausible entitlement to relief." *Eclectic Props. E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 998 (9th Cir. 2014) (quoting *Iqbal*, 556 U.S. at 678).

Because Plaintiffs accuse defendants of engaging in "fraudulent" conduct (*e.g.*, Complaint ¶ 4), and conduct sounding in fraud, the Complaint is also subject to Rule 9(b)'s heightened pleading requirements. *Kearns v. Ford Motor Co.*, 567 F.3d 1120,

1126 (9th Cir. 2009). As a result, Plaintiffs must specify "the who, what, when, where, and how" of the allegedly fraudulent conduct. *Id.*

As discussed below, the Complaint fails to state a claim and should be dismissed on four independent grounds beyond Plaintiffs' lack of standing: (1) Plaintiffs' claims are barred by the statutes of limitations, (2) the FDCA preempts Plaintiffs' claims, (3) Plaintiffs fail to plausibly allege the Purported Zicam PE Products were falsely advertised, and (4) Plaintiffs do not plead any allegedly fraudulent conduct with particularity.

1. Plaintiffs' Claims Based on Purported Purchases from Over a Decade Ago Are Time-Barred

No Zicam PE Product has been marketed in the U.S. since at least 2010. As a result, Plaintiffs' claims are necessarily based on purchases that, if they occurred at all, must have taken place well over a decade ago. The statutes of limitations on Plaintiffs' causes of action therefore bar all their claims.[10] Plaintiffs claim the statutes of limitations should be tolled either because of the discovery rule or on a fraudulent concealment theory. But Plaintiffs do not plead facts to support either of these potential bases for tolling, nor can they do so in an amended pleading.

"In order to invoke the discovery rule, the plaintiff must plead and prove facts showing: (a) lack of knowledge; (b) lack of means of obtaining knowledge (in the exercise of reasonable diligence the facts could not have been discovered at an earlier date); and (c) how and when he did actually discover the fraud or mistake." *Saaremets v. Whirlpool Corp.*, 2010 U.S. Dist. LEXIS 26165, at *16 (E.D. Cal. Mar. 18, 2010).

The standard for fraudulent concealment is similar in that "a plaintiff must plead the following: '(1) when the fraud was discovered; (2) the circumstances under which it was discovered; and (3) that the plaintiff was not at fault for failing to discover it or

[10] The statutes of limitations on Plaintiffs' claims run between two and four years. CAL. CIV. CODE § 1783 (West) (three years); CAL. CIV. PROC. CODE § 338(d) (West) (three years), CAL. UNIF. COM. CODE § 2725 (West) and UNIF. COM. CODE § 2-725 (West) (four years); CAL. CIV. PROC. CODE § 335.1 (West) (two years), CAL. BUS. & PROF. CODE § 17208 (West) (four years).

had no actual or presumptive knowledge of facts sufficient to put him on inquiry.'" *Id.* at *19-20 (quoting *Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1024 (9th Cir. 2008)). "Moreover, 'the plaintiff must point to some fraudulent concealment, some active conduct by the defendant *above and beyond* the wrongdoing upon which the plaintiff's claim is filed, to prevent the plaintiff from suing in time.'" *Garcia v. GM LLC*, 2018 U.S. Dist. LEXIS 208129, at *22 (E.D. Cal. Dec. 10, 2018) (emphasis in original) (quoting *Lukovsky v. City & Cnty. of San Francisco*, 535 F.3d 1044, 1052 (9th Cir. 2008)). Allegations of fraudulent concealment are subject to Rule 9(b)'s particularity requirement. *Id.* at *21; *Johnson v. Glock, Inc.*, 2021 U.S. Dist. LEXIS 93555, at *9 (N.D. Cal. May 17, 2021).

An illustrative case is *Plumlee v. Pfizer, Inc.*, 2014 U.S. Dist. LEXIS 121634 (N.D. Cal. Aug. 29, 2014). There, the plaintiff alleged she was deceived by false and misleading statements about the efficacy of Zoloft for treating depression. *Id.* at *3. But the plaintiff last bought the product in 2008 and sued in 2013, so her claims were time-barred. *Id.* at *20. The court dismissed the complaint, finding that plaintiff failed to adequately allege discovery rule tolling. She "fail[ed] to identify any actions [she] took to investigate the alleged wrongful conduct by Pfizer at the time a reasonable person should have suspected wrongdoing." *Id.* at *23. Notably, she had used Zoloft and thus was familiar with its efficacy, or lack thereof, to treat her depression. *Id.* at *26. Also, there were media publications and scientific articles that questioned the efficacy of Zoloft. *Id.* at *29-30. As a result, the court held that "although Plaintiff can and does plead she was ignorant of any information, she cannot plead that such information was unavailable to a reasonably diligent consumer." *Id.* at *31-32. The court dismissed the complaint with prejudice. *Id.* at *34.

This case is just like *Plumlee* but with even more years of inexcusable delay. As in *Plumlee*, Plaintiffs here do not allege any steps they took to investigate the efficacy of phenylephrine. Nor do Plaintiffs explain why they could not have discovered the well-publicized doubts about phenylephrine over the years, which, as in *Plumlee*, were

the subject of media coverage, scientific articles, and other public debate. *See* pp. 5-6, *supra*. While it is conceivable that Plaintiffs were unaware of this matter until the most recent headlines, they certainly could have discovered this issue long ago with even a scrap of due diligence. And if phenylephrine products really do not clear nasal congestion, Plaintiffs should have realized this when they used the products.[11] Thus, Plaintiffs do not and cannot adequately plead discovery rule tolling or fraudulent concealment.

Plaintiffs' fraudulent concealment allegations also fail because Plaintiffs do not allege, never mind with particularity, *anything* that Church & Dwight or Zicam did to conceal the alleged inefficacy of the Purported Zicam PE Products. *See Saaremets*, 2010 U.S. Dist. LEXIS 26165 at *22 (rejecting conclusory allegations of fraudulent concealment because "there are no facts in plaintiff's complaint that suggest Whirlpool used deceptive practices to prevent plaintiff or other customers from using the [product] or discovering its alleged deficiency"). That is because nothing was concealed. Like any other consumer product, the Purported Zicam PE Products were "marketed and readily available for testing by a plaintiff." *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 107 Cal. App. 4th 1336, 1348 (Ct. App. 2003). And, assuming that the Purported Zicam PE Products contain phenylephrine as Plaintiffs claim, they would have been labeled as containing phenylephrine (and with all other language required by the OTC Monograph). Thus, it was only Plaintiffs' own lack of diligence that prevented them from suing with respect to the Purported Zicam PE Products many years ago. Plaintiffs' claims against Church & Dwight are therefore time-barred and should be dismissed with prejudice.

2. In Light of the OTC Monograph Applicable to the Purported Zicam PE Products, the FDCA Preempts Plaintiffs' Claims

Plaintiffs' claims are all brought under state law. The federal FDCA expressly preempts state law to the extent that it would impose any requirement relating to an

[11] Notably, Plaintiffs do not allege they used the Purported Zicam PE Products and the products failed to clear their nasal congestion, which is one reason they lack standing to sue Church & Dwight.

OTC drug "that is different from or in addition to, or that is otherwise not identical to" a requirement under the FDCA. 21 U.S.C. § 379r(a). State law is also impliedly preempted when it actually conflicts with federal law, *Geier v. American Honda Motor Co.* 529 U.S. 861, 884 (2000), or when federal law thoroughly occupies the field, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). As explained below, Plaintiffs' claims are both expressly and impliedly preempted by the FDCA.

OTC drugs like the Purported Zicam PE Products are regulated under FDA's OTC Monograph, which allows manufacturers to sell a new OTC drug without individualized review. The OTC Monograph "was promulgated by the FDA based on a process that involved the recommendation of an advisory panel of independent experts, which evaluated the safety and effectiveness of OTC drugs with numerous opportunities for public notice and comment." *Carter v. Novartis Consumer Health Inc.*, 582 F. Supp. 2d 1271, 1276 (C.D. Cal. 2008). "Monographs set 'the FDA-approved active ingredients for a given therapeutic class of OTC drugs and provide[] the conditions under which each active ingredient is' GRASE [generally recognized as safe and effective]." *Truss v. Bayer Healthcare Pharms. Inc.*, 2022 U.S. Dist. LEXIS 207421, at *7-8 (S.D.N.Y. Nov. 15, 2022).

Given FDA's extensive regulation of OTC drug products through the OTC Monograph, courts regularly dismiss claims like Plaintiffs' as preempted. Particularly instructive here is *Carter*. There, plaintiffs sued the makers of OTC cough and cold products—including nasal decongestants containing phenylephrine—for alleged economic harm resulting from having bought products that "do not work." 582 F. Supp. 2d at 1276-77. The suit was prompted by "an FDA Advisory Panel['s] recommend[ation] that those medicines not be used in children under six," which FDA adopted in part. *Id.* at 1276. But all the products in that suit were sold under the OTC Monograph, through which FDA prescribes the labeling for the products. *Id.* The court therefore dismissed the case, holding that "claims based upon FDA-approved statements in product labeling and advertising are preempted." *Id.* at 1286.

Other examples of preemption based on FDA monographs abound. Claims challenging the veracity of a cough suppressant's "non-drowsy" label statement were preempted because "such labeling complies with the FDA's [OTC] Monograph." *Amara v. Publix Supermarkets, Inc.*, 2022 U.S. Dist. LEXIS 145598, at *12 (M.D. Fla. Aug. 12, 2022). A plaintiff was "preempted from making claims regarding the safety and efficacy of fluoride in the Charcoal Toothpastes because the FDA has issued a monograph regarding the efficacy of fluoride." *Housey v. P&G*, 2022 U.S. Dist. LEXIS 53603, at *13, n.9 (S.D.N.Y. Mar. 24, 2022). And "claims [were] expressly preempted by FDCA labeling requirements for sunscreen [as set forth in a monograph for sunscreen products], to the extent they result from the Product label's omission of [an allegedly dangerous ingredient]." *Truss*, 2022 U.S. Dist. LEXIS 207421 at *9.

Just as in the above cases, FDA has carefully and pervasively regulated OTC cold products, including the Purported Zicam PE Products, and has set forth labeling requirements for such products. The OTC Monograph approves of such products being marketed as "nasal decongestants." There is no allegation that the Purported Zicam PE Products violated the OTC Monograph, nor could Plaintiffs make such allegations. Plaintiffs are therefore trying to use state law to impose requirements that differ from, and conflict with, FDA's labeling requirements, and are trying to usurp FDA's exclusive jurisdiction to regulate OTC cold products. Accordingly, Plaintiffs' claims that challenge FDA-approved product labeling are all preempted and should be dismissed with prejudice.

3. Plaintiffs Do Not Adequately Allege the Purported Zicam PE Products Were Ineffective for their Advertised Purpose

"It is well settled that private litigants may not bring false advertising claims based on an alleged lack of substantiation." *Yamasaki v. Zicam LLC*, 2021 U.S. Dist. LEXIS 205494, at *12 (N.D. Cal. Oct. 25, 2021) (citing *King Bio*, 107 Cal. App. 4th at 1345). To survive a motion to dismiss, a plaintiff must allege facts that plausibly

support an inference that the challenged advertising is false, not merely unsubstantiated. *Kwan v. Sanmedica Int'l*, 854 F.3d 1088, 1098 (9th Cir. 2017).

The Complaint here lacks such facts. There are no allegations about the Purported Zicam PE Products themselves, never mind factual allegations that tend to show the products did not work as advertised. Indeed, Plaintiffs do not even allege that they used the Purported Zicam PE Products as directed (or at all) and the products failed to work for them.

The Complaint's only factual allegation about the alleged inefficacy of orally administered phenylephrine is that "[o]n or about September 12, 2023, the Federal Drug Administration [sic], after careful study and consideration, announced publicly that phenylephrine is ineffective as a treatment for [nasal congestion]." Complaint ¶ 3. But the announcement that the Complaint references (and thus incorporates by reference) *refutes Plaintiffs' allegation*. The announcement came from an FDA advisory committee, not FDA itself. Ex. 1. It says that FDA "makes the final decision" and FDA "will consider the input of this advisory committee, and the evidence, *before taking any action* on the status of oral phenylephrine." *Id.* (emphasis added). And the advisory committee did not state that "phenylephrine is ineffective," as Plaintiffs allege, but merely expressed concern "that *the current scientific data do not support* that the recommended dosage of orally administered phenylephrine is effective as a nasal decongestant." *Id.* (emphasis added). Thus, the Complaint grossly mischaracterizes the announcement.

As discussed, it is Plaintiffs' burden to plausibly allege *falsity*—not just uncertainty. *Kwan*, 854 F.3d at 1098. But the most that Plaintiffs could allege is that whether the existing scientific data support phenylephrine being an effective nasal decongestant is up for debate. Such allegations fall short of supporting an inference of falsity. *See Housey*, 2022 U.S. Dist. LEXIS 53603 at *12-13 (holding that a scientific review's conclusion that there is "insufficient clinical and laboratory data" did not

support an inference of falsity). Thus, the Complaint fails to state any claim for relief that the Purported Zicam PE Products failed to perform as advertised.

4. Plaintiffs' Claims Fail under Rule 9(b) Because They Do Not Allege the Circumstances of the Alleged Fraud with Particularity

The Complaint also violates Rule 9(b)'s particularity requirement. A plaintiff alleging fraud or claims sounding in fraud must specify the circumstances of their purchase, including the "who, what, when, where, and how of the misconduct alleged." *Kearns*, 567 F.3d at 1126. In the case of a complaint alleging false advertising or deceptive labeling, this means identifying "what the [challenged advertisements or labels] specifically stated," "when [the plaintiff] was exposed to them," and "which sales material [the plaintiff] relied upon." *Id.*

Applying this precedent, courts routinely dismiss complaints that fail to identify which advertising or labeling statements the plaintiff saw and relied on, and when and where they saw those statements and bought the product in question. *See, e.g.*, *Robinson v. Unilever U.S.*, 2018 U.S. Dist. LEXIS 225254, at *17-19 (C.D. Cal. June 25, 2018) ("Plaintiff fails to allege with specificity the circumstances under which she was exposed to the statements at issue" by alleging that "[i]n the last several years," Plaintiff "made several purchases of St. Ives Body Lotion and St. Ives Body Wash from various stores in and near Los Angeles and San Diego, California"); *Alvarez v. NBTY, Inc.*, 2017 U.S. Dist. LEXIS 201159, at *27-28 (S.D. Cal. Dec. 6, 2017) ("Plaintiff Lesher only provides a few vague factual allegations relating to her purchase of the Products. She states she resided in St. Charles, IL during 'the relevant time period' (but does not provide these dates); was 'exposed to, saw, and relied on' the representations on 'the Product label in Illinois' (but does not provide a county, city, and/or store name); and purchased the Product (but does not provide any information about where or how she purchased the Product)"); *Flowers v. Doctor's Best, Inc.*, 2014 U.S. Dist. LEXIS 206644, at *14-15 (C.D. Cal. June 13, 2014) ("[T]he FAC does not identify which of the Supplements Flowers and Standard purchased, and thus it is not clear whether

Plaintiffs purchased one of the three products specifically identified in the FAC or some other of 'Doctor's Best brand Supplements'").

Beyond Plaintiffs' failure to identify the specific Purported Zicam PE Products that they bought, if any, they also describe none of the circumstances surrounding such alleged purchases. Plaintiffs do not say what advertising or labeling statements they saw and relied on, where those statements appeared, or when and where they bought the products. The date of each Plaintiff's alleged purchase is paramount because, as discussed above, Plaintiffs' claims are barred by the relevant statutes of limitations. Yet there is no indication even in what decade Plaintiffs purport to have bought the Purported Zicam PE Products. And Plaintiffs provide no details in support of their conclusory assertion that "each such Defendant knew that phenylephrine and the Phenylephrine Products were entirely ineffective against congestion and the associated cold & flu symptoms the Phenylephrine Products were advertised to treat." Complaint ¶ 55. Thus, the Complaint should be dismissed under Rule 9(b) for lack of particularity.

C. If the Court Does Not Dismiss the Complaint in its Entirety, It Should Stay this Case Under the Doctrine of Primary Jurisdiction

For the reasons discussed above, Plaintiffs' claims against Church & Dwight should be dismissed with prejudice. If the Court is not prepared to do so, it should stay this case until FDA decides whether orally administered phenylephrine is effective.

To decide whether to apply the doctrine of primary jurisdiction, courts weigh "(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Syntek Semiconductor Co. v. Microchip Tech. Inc.*, 307 F.3d 775, 781 (9th Cir. 2002). Courts frequently invoke the primary jurisdiction doctrine when "determination of a plaintiff's claim would require a court to decide an issue committed to the FDA's expertise without a clear indication of how the FDA would view the issue." *Figy v. Lifeway Foods, Inc.*, 2014 U.S. Dist. LEXIS 62700,

at *6 (N.D. Cal. May 5, 2014) (quoting *Hood v. Wholesoy & Co.*, 2013 U.S. Dist. LEXIS 97836, at *14 (N.D. Cal. July 12, 2013)).

All these factors support deferring to FDA here. The efficacy of phenylephrine is a matter uniquely within FDA's realm of expertise and discretion. FDA has comprehensively regulated phenylephrine products for decades under the OTC Monograph, and recently identified this subject in its annual forecast as a "planned monograph activit[y]" that FDA intends to address. Ex. 22. FDA has also recently stated, in response to the concerns from its advisory committee, that it will consider the committee's input and the evidence and then make its own decision about the status of orally administered phenylephrine. Ex. 1. If FDA ultimately concludes that phenylephrine is not effective, it would then issue a proposed order removing it from the OTC Monograph that would be open for public comment before any final order. *Id.* No matter what FDA decides to do, there is a substantial danger that its actions and determinations will conflict with any ruling in this Court.

This situation parallels other cases in which courts have stayed or dismissed an action in deference to FDA's ongoing decision-making process. *E.g.*, *Gisvold v. Merck & Co., Inc.*, 62 F. Supp. 3d 1198, 1204 (S.D. Cal. 2014) (dismissing claims challenging sunscreen products labeled above SPF 50 because FDA was evaluating the clinical benefit of such products and had issued a proposed rule seeking comments); *Figy*, 2014 U.S. Dist. LEXIS 62700 at *10-13 (staying action that alleged the term "evaporated cane juice" was deceptive because FDA issued a notice seeking comment on this term). Just as in these cases, FDA's statements that it is investigating the very issue raised in Plaintiffs' Complaint—whether orally administered phenylephrine is an effective nasal decongestant—strongly favors staying this case if it survives outright dismissal.

IV. CONCLUSION

For the above reasons, the Court should dismiss the entire Complaint with prejudice. In the alternative, the Court should permit Church & Dwight to renew its

Rule 12(b)(1) motion following jurisdictional discovery from Plaintiffs, and otherwise should stay the case pending FDA's review of phenylephrine products.

Dated: November 7, 2023

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